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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/668,077	09/22/2003	K.T. Venkateswara Rao	ACS 63118 (3624X)	1259
7590 05/21/2007 CAMERON KERRIGAN SQUIRE, SANDERS & DEMPSEY L.L.P. ONE MARITIME PLAZA SUITE 300 SAN FRANCISCO, CA 94111-3492			EXAMINER SNOW, BRUCE EDWARD	
			ART UNIT 3738	PAPER NUMBER
			MAIL DATE 05/21/2007	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

8P

# Office Action Summary

Application No.

10/668,077

Applicant(s)

RAO, K.T. VENKATESWARA

Examiner

Bruce E. Snow

Art Unit

3738

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 07 March 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-16 and 19-26 is/are pending in the application.
- 4a) Of the above claim(s) 3,5,7,8 and 19-25 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,2,4,9-16 and 26 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- |                                                                                                                       |                                                                                         |
|-----------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                           | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                  | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____                                                |

## DETAILED ACTION

### *Response to Arguments*

Applicant's arguments filed 3/7/07 have been fully. Regarding the IDS dated 9/1/04, per applicant's request, a copy of the IDS and page 3 of the contents of the current application showing said IDS are attached as Exhibit 1.

Regarding the rejection under 35 U.S.C. 102(e) as being anticipated by Vallana et al (2003/0078647), applicant arguments are persuasive.

Regarding the rejection under 35 U.S.C. 102(b) as being anticipated by Tartaglia et al (5,700,286), applicant states that the drug loaded elements are not independent. It is the Examiner's position that the slits 30 produce independent elements even though they are attached at a first end. Applicant's claim language does not exclude this configuration. Each free end allows the element to move **independent** from the others and are therefore considered independent. Tartaglia states, "*the film of polymeric material also has a free end 28, and can have one or more slits 30 in the polymeric film transverse to the axis 32 of the stent to accommodate possible uneven expansion of the underlying stent structural member (4:37 et seq.)*". The Examiner suggests the following to overcome the rejection, "having independent **discrete** drug-loaded elements".

Quick definitions (***discrete***)

- ***adjective***: constituting a separate entity or part

Quick definitions (***independent***)

- ***noun***: a writer or artist who sells services to different employers without a long-term contract with any of them

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- **noun:** a neutral or uncommitted person (especially in politics)
- **adjective:** not dependent on or conditioned by or relative to anything else
- **adjective:** not contingent
- **adjective:** free from external control and constraint (Example: "An independent mind")
- **adjective:** of a clause; able to stand alone syntactically as a complete sentence (Example: "The main (or independent) clause in a complex sentence has at least a subject and a verb")
- **adjective:** not controlled by a party or interest group
- **adjective:** of political bodies

It is the Examiner's unyielding position that the elements of Tartaglia are "not dependent on or conditioned by" each other and are allowed to unroll independently.

Regarding "wherein the sleeve is not stretched when the stent structure expands.." this is functionally language and does not have to occur while in the body lumen. It is the Examiner's position that the elements of Tartaglia do not have to stretch when expanded outside of a lumen. Additionally, the elements unroll and don't have to stretch.

Regarding the rejection under 35 U.S.C. 103(a) as being unpatentable over Williams (5,707,385) in view of Tartaglia et al (5,700,286), the Examiner respectfully disagrees with applicant, the membrane does not have to stretch when the stent is expanded; as noted, column 2, lines 30-41 state "sliding or stretching". Regarding the argument about independent elements, see the Examiner's position above.

### ***Claim Rejections - 35 USC § 112***

Claims 1, 2, 4, 6, 9-18, 26 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably

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convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Regarding claim 1, "The tubular sleeve being releasably attached to an outer surface of a stent structure in an unexpanded condition, at least a portion of the patterned tubular sleeve portion being decoupled from the outer surface of the stent when the stent is in an expanded condition".

***Allowable Subject Matter***

Note claim 6 is not rejected in view of art.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 1, 2, 4, 9-18, 26 are rejected under 35 U.S.C. 102(e) as being anticipated by Herweck et al (2003/0153901).

1. (previously presented) A sleeve loaded 12 with at least one therapeutic drug for the eventual release thereof at a treatment site within a body lumen, comprising:

a prefabricated patterned tubular sleeve portion having independent drug-loaded elements 12, 12A, etc., the tubular sleeve being releasably attached to an outer surface of a stent structure in an unexpanded condition (note teaching of electrostatically coupled in a temporary manner and 14-15), at least a portion of the patterned tubular sleeve portion being decoupled from the outer surface of the stent when the stent is in an expanded condition so that the independent drug-loaded elements are held against the body lumen by at least a portion of the patterned tubular sleeve portion, wherein the sleeve is not stretched when the stent structure expands from the unexpanded condition to the expanded condition.

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Claims 1, 2, 4, 9-18, 26 are rejected under 35 U.S.C. 102(b) as being anticipated by Tartaglia et al (5,700,286).

Tartaglia et al teaches a sleeve loaded with at least one therapeutic drug for the eventual release thereof at a treatment site within a body lumen, comprising:

a prefabricated patterned tubular sleeve portion (generally element 5) having independent drug-loaded elements separated by slits 30, the tubular sleeve being releasably attached to an outer surface of a stent structure 22 in an unexpanded condition (via friction), at least a portion of the patterned tubular sleeve portion being decoupled from the outer surface of the stent when the stent is in an expanded condition so that the independent drug-loaded elements are held against the body lumen by at least a portion of the patterned tubular sleeve portion.

Regarding claim 1 and 18, the stent is interpreted as being positively claimed.

Regarding claim 9, the claim only claims a portion of the sleeve has to be unattached in the unexpanded and expanded condition which a portion clearly is.

Claim 12 is interpreted as describing the struts of the stent.

Claim 15, the same materials inherently have the same characteristics.

Regarding claim 17, for this rejection the Examiner has interpreted the claim as not positively claiming the stent. Therefore, the sleeve by itself before it is connected to the stent is fully capable of fulfilling the claim language. Additionally, the claim is claiming only portion of the sleeve has to be unattached in the unexpanded condition and the expanded condition which it clearly is.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims are 1, 2, 4, 9-18, 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Williams (5,707,385) in view of Tartaglia et al (5,700,286).

Williams teaches a sleeve loaded with at least one therapeutic drug for the eventual release thereof at a treatment site within a body lumen, comprising:

a prefabricated patterned tubular sleeve portion 5 being releasably attached to an outer surface of a stent structure in an unexpanded condition, at least a portion of the patterned tubular sleeve portion being decoupled from the outer surface of the stent when the stent is in an expanded condition. However, Williams is silent regarding the sleeve having independent drug-loaded elements. Tartaglia et al teaches a similar sleeve comprising independent elements separated by slits 30. It would have been obvious to one having ordinary skill in the art to have utilized the slits 30 of Tartaglia et al on the tubular sleeve of Williams "to accommodate possible uneven expansion of the underlying stent structural member (4:40-41)".

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bruce E. Snow whose telephone number is (571) 272-4759. The examiner can normally be reached on Mon-Thurs.




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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on (571) 272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

bes



**BRUCE SNOW**  
**PRIMARY EXAMINER**

Exhibit 1 1/4

10/668077

Examiner: SNOW, BRUCE

GAU: 3738

Inventor: RAO, K.T.

Classification: 623/001.150

Status: 71 - RESPONSE TO NON-FINAL OFFICE ACTION ENTERED AND FORWARDED TO EXAMINER

Title: DRUG-ELUTING STENT AND METHODS OF MAKING

All tab report (70 items, sorted by Date DESC)

Img	Status	Doc Code	Document Type	Date	Pages	Annotations
	7	NPL	NPL Documents	03/22/2006	6	
	7	NPL	NPL Documents	03/22/2006	6	
	7	NPL	NPL Documents	03/22/2006	6	
	7	NPL	NPL Documents	03/22/2006	11	
	7	NPL	NPL Documents	03/22/2006	12	
	7	NPL	NPL Documents	03/22/2006	11	
	7	NPL	NPL Documents	03/22/2006	6	
	7	NPL	NPL Documents	03/22/2006	10	
	7	NPL	NPL Documents	03/22/2006	8	
	7	NPL	NPL Documents	03/22/2006	15	
	7	NPL	NPL Documents	03/22/2006	6	
	7	NPL	NPL Documents	03/22/2006	9	
	7	ELC.	Response to Election / Restriction Filed	03/08/2006	2	
	7	XT/	Extension of Time	03/08/2006	1	
	7	TRTC	Transmittal to TC	03/08/2006	2	
	7	CTRS	Requirement for Restriction/Election	11/08/2005	6	
	7	LET.	Miscellaneous Incoming Letter	01/13/2005	2	
	7	TRTC	Transmittal to TC	01/13/2005	2	
	7	IDS	Information Disclosure Statement (IDS) Filed	09/01/2004	3	
	7	CTMS	Miscellaneous Action with SSP	06/29/2004	1	
	7	CTMS	Miscellaneous Action with SSP	06/29/2004	1	

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PTO/SB/21 (08-03)

Approved for use through 07/31/2006. OMB 0851-0031

Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

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<b>TRANSMITTAL FORM</b> <i>(to be used for all correspondence after initial filing)</i>	Application Number	10/668,077	
	Filing Date	September 22, 2003	
	First Named Inventor	K.T. Venkateswara Rao	
	Art Unit	3731	
	Examiner Name	Unassigned	
Total Number of Pages in This Submission	7	Attorney Docket Number	ACS 63118

ENCLOSURES (check all that apply)		
<input type="checkbox"/> Fee Transmittal Form <input type="checkbox"/> Fee Attached <input type="checkbox"/> Amendment / Reply <input type="checkbox"/> After Final <input type="checkbox"/> Affidavits/declaration(s) <input type="checkbox"/> Extension of Time Request <input type="checkbox"/> Express Abandonment Request <input checked="" type="checkbox"/> Information Disclosure Statement <input type="checkbox"/> Certified Copy of Priority Document(s) <input type="checkbox"/> Response to Missing Parts/Incomplete Application <input type="checkbox"/> Response to Missing Parts under 37 CFR 1.52 or 1.53	<input type="checkbox"/> Drawing(s) <input type="checkbox"/> Licensing-related Papers <input type="checkbox"/> Petition <input type="checkbox"/> Petition to Convert a Provisional Application <input type="checkbox"/> Power of Attorney, Revocation <input type="checkbox"/> Change of Correspondence Address <input type="checkbox"/> Terminal Disclaimer <input type="checkbox"/> Request for Refund <input type="checkbox"/> CD, Number of CD(s) _____	<input type="checkbox"/> After Allowance communication to Group <input type="checkbox"/> Appeal Communication to Board of Appeals and Interferences <input type="checkbox"/> Appeal Communication to Group (Appeal Notice, Brief, Reply) <input type="checkbox"/> Proprietary Information <input type="checkbox"/> Status Letter <input checked="" type="checkbox"/> Other Enclosure(s) (please identify below): <div style="border: 1px solid black; padding: 2px; margin-top: 5px;">Postcard</div>
Remarks <span style="float: right;">24201</span>		

SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT	
Firm or Individual name	FULWIDER PATTON LEE & UTECHT, LLP
Signature	<i>John Nagy</i>
Date	January 15, 2004

CERTIFICATE OF TRANSMISSION/MAILING			
I hereby certify that this correspondence is being facsimile transmitted to the USPTO or deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on			
Typed or printed name	JOHN S. NAGY, ESQ.		
Signature	<i>John Nagy</i>	Date	January 15, 2004


This collection of information is required by 37 CFR 1.5. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

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CERTIFICATE OF MAILING UNDER 37 C.F.R. § 1.8

I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as First Class Mail in an envelope addressed to: Commissioner for Patents, P. O. Box 1450, Alexandria, VA 22313-1450 on January 15, 2004

  
John S. Nagy, Reg. No. 20064

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Appl. No. : 10/668,077  
Applicant : K.T. Venkateswara Rao  
Filed : September 22, 2003  
Art Unit : 3731  
Examiner : Unassigned  
Title : DRUG-ELUTING STENT AND METHODS OF MAKING  
Docket No.: : ACS 63118 (3624X)  
Customer No. : 24201

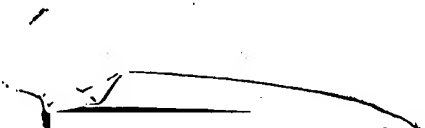
*IFW*

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

INFORMATION DISCLOSURE STATEMENT

Dear Sir:

The documents listed on the enclosed Forms PTO/SB/08A have come to the attention of Applicants and are submitted to the Office under 37 C.F.R. § 1.97(c) (3) and § 1.98(d). Enclosed is a copy of an Information Disclosure Statement (with Form PTO/SB/08A) as filed in the parent application, U.S. Serial No. 10/293,108 filed November 13, 2002. The references listed were previously submitted in parent application Serial No. 10/293,108. It is believed that these references will be helpful during examination of the application.



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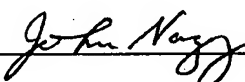
This application is a continuation in part of U.S. Serial No. 10/293,108 filed on November 13, 2002. A copy of the documents listed on the Information Disclosure Statement by Applicant Form PTO/SB/08A can be found in U.S. Serial No. 10/293,108.

Applicants believe that this Information Disclosure Statement has been filed before the mailing date of a first Office action on the merits in accordance with 37 C.F.R. § 1.97(b)(3) and therefore, no fee is due. However, if a fee is in fact due the Commissioner is authorized to charge our Deposit Account No. 06-2425. A duplicate of this paper is enclosed.

Respectfully submitted,

FULWIDER PATTON LEE & UTECHT, LLP

By:

  
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Registration No. 30,664

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